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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,588	10/15/2002	Leszek Wojnowski	VOS-31	7619

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EXAMINER

CHANDRA, GYAN

ART UNIT PAPER NUMBER

1646

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/070,588	Applicant(s) WOJNOWSKI ET AL.	
	Examiner Gyan Chandra	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 4-37 is/are pending in the application.
- 4a) Of the above claim(s) 9-33 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-8, 34, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of Application, Amendments, And/Or Claims**

Claims 2-3 are canceled. The amendment of claims 1, 4, 6, 8 and 36 has been made of record.

Claims 1 and 4-37 are pending. Claims 9-33, and 35 are withdrawn from further consideration as being drawn to a nonelected Invention.

Claims 1, 4-8, 34, and 36-37 are examined on the merit to the extent that they read on the elected invention.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Response to Arguments***

#### **Objection/Rejection - withdrawn**

The objection to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code (see page 32) is withdrawn due to deletion of embedded hyperlink as filed on 9/8/2005.

The objection to claims 3-8, and 36-37 under 37 CFR 1.75(c) as being in improper form because of multiple dependent claims 3-8, and 36-37 is withdrawn due to Applicant's cancellation of claims 3 and amendment to the claims for a proper multiple dependencies and they are now being examined.

#### **Objection/Rejection – maintained**

The rejection of claims 1, 4-8, 34 and 36-37 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The claims are drawn to a polynucleotide encoding any variant human PXR polypeptide or fragment thereof wherein the polynucleotide comprises nucleic acid sequence of SEQ ID NO: 112.

The claim does not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or any other disclosed distinguished feature. Therefore, claims encompass enumerable variants of human PXR (2.9 Kb gene) that comprise SEQ ID NO: 112 (11 base pairs). Thus the claims are drawn to a genus of nucleic acids that is defined solely by sequence identity.

The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the chemical product, or any combination thereof. There is not even identification of any particular portion of the structure that must be conserved. Further, the recited activity of a hPXR variant as the activation by rifampicin (page 36-37) is not specific because specification does not disclose any significant effect on variants. Also, specification does not suggest what activity to correlate with any variant. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Applicant argues that the specification discloses at least a single a species of a variant hPXR polypeptide at position D163G that leads to a reduced level of transcription activity as evidenced by rifampicin treatment (Figure 6A). Therefore, the instant application teaches structure function relationship requirement of the written description.

Applicant's arguments have been fully considered but they are not persuasive because claims are drawn to a genus of nucleic acids without any functional limitation. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the chemical product, or any combination thereof. There is not even identification of any particular portion of the structure that must be conserved. Further, the recited activity of the hPXR variant as the activation by rifampicin (page 36-37) is not specific because specification does not disclose any significant effect on variants. Also, specification does not suggest which residues are essential for the hPXR transcriptional activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

### ***Claim Rejections - 35 USC § 102***

The rejection of 1 under 35 U.S.C. 102(b) as being anticipated by Hwang et al (Genomics 30: 293298, 1995; Accession R57583, GI: 827441) is maintained for the reasons of records.

Claim is drawn to an isolated polynucleotide encoding a variant hPXR polypeptide or fragment thereof wherein the polynucleotide comprises nucleotide of SEQ ID NO: 112.

Applicants argue that the variant has impaired transcriptional activity upon treatment with rifampicin.

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Applicants' argument has been considered but it is not persuasive because the claims are drawn to nucleic acid encoding to the hPXR variant or fragment thereof. Claim does not require any functional limitation for the hPXR variant or its fragment. Hwang et al teach a polynucleotide sequence GI: 827441 expressed in a human fetal heart library which is 100% identical to the polynucleotide sequence of SEQ ID NO: 112 of the instant application (see previous Office Action).

The rejection of 1, 4-8, 34, and 36-37 under 35 U.S.C. 102(e) as being anticipated by Mittman et al (U S Patent No. 6821724) is maintained for the reasons of records.

Claim is drawn to an isolated polynucleotide encoding a variant hPXR polypeptide or fragment thereof wherein the polynucleotide comprises nucleotide of SEQ ID NO: 112.

Applicants argue that Mittman teaches 100% identical sequence to the nucleic acid sequence of SEQ ID NO: 112 but the disclosed sequence of Mittman is not within the hPXR gene.

Applicants arguments have been fully considered but they are not persuasive because claim is drawn to a nucleic acid encoding a variant of hPXR or fragment thereof wherein the polynucleotide comprises nucleotide of SEQ ID NO: 112. Mittman et al teach a polynucleotide sequence, which is 100% identical to the nucleic acid sequence of SEQ ID NO: 112 (see Office Action mailed on 4/8/2005). They teach a vector comprising a polynucleotide sequence having the nucleic acid sequence of SEQ

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ID NO: 112, expressing protein to perform assay (column 8, lines 11-15), a composition and the use of nucleic acid in diagnostics (Column 1, lines 19-23).

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra, Ph.D.  
Art Unit 1646  
03 November 2005  
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JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER